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FSIS BACKGROUNDER



Poultry Irradiation and Preventing Foodborne Illness

The Proposal

On September 21, 1992, the U.S. Department of Agriculture approved a rule to permit irradiation of raw, packaged poultry to control certain common bacteria on raw poultry that can cause illness when poultry is undercooked or otherwise mishandled. The rule permits irradiation of prepackaged fresh or frozen poultry at 1.5 to 3.0 kiloGray, the smallest, most practical "dose" of irradiation for bacterial control, with the goal of reducing the potential for foodborne illness.

The Food Safety and Inspection Service (FSIS), which is responsible for ensuring that meat and poultry products are safe, wholesome and accurately labeled, is the USDA agency approving the rule. The Food and Drug Administration (FDA) has confirmed that poultry irradiation is safe. FDA's approval is consistent with the views of the scientific community. Internationally, the Joint Expert Committee on Food Irradiation (which was made up of representatives from the World Health Organization of the United Nations and the International Atomic Energy Agency) is among many groups that endorsed the use of food irradiation.

FSIS wholeheartedly accepts the FDA determination. The role of FSIS is to determine how poultry irradiation could be carried out effectively.

The USDA rule will permit approved plants to irradiate retail and wholesale packages of fresh or frozen poultry (including such uncooked products as whole or cut-up birds, ground, hand-boned and skinless poultry.)

Salmonella, *Campylobacter jejuni*, and *Listeria monocytogenes* are found throughout the environment, especially on the farm, and in the intestines and on the skin and feathers of some chickens and turkeys (as well as other animals). If the poultry is mishandled — anywhere from the farm to the dinner table — the bacteria can multiply, and can cause illness in some people who eat the contaminated foods. (Thorough cooking destroys the bacteria and prevents illness.)

Irradiation in the range approved in the rule would eliminate from 99.5 to 99.9 percent of the *Salmonella* organisms on the treated poultry. Recent studies suggest that the sensitivity to irradiation is similar for *Salmonella* and *Listeria monocytogenes*. Therefore doses effective for *Salmonella* would also destroy *Listeria* bacteria. That fact has food safety importance, because *Listeria* contamination is difficult to control. *Listeria* multiply slowly even at refrigeration temperatures.

Fresh/Frozen Poultry Only

The Problem: Potentially Harmful Bacteria

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Irradiation Plus Safe Food Handling

Irradiation at the approved level would not necessarily destroy every single bacterial cell present; it would not sterilize the food. After treatment, any surviving organisms could start to multiply again if conditions are favorable. Open packages of irradiated poultry could also be recontaminated; for example, if a food handler were to omit washing his/her hands after using the bathroom and then were to touch the poultry.

Therefore, food handlers would have to handle irradiated poultry as carefully as all other foods.

Labeling Requirements



The new rule requires packages of irradiated poultry to carry the green, international radiation logo as well as the words “*Treated with Radiation*” or “*Treated by Irradiation*.” Those words are to be in letters of the same style, color, and type as the product name and to be no less than one-third the size of the largest letter in the product name.

As is the rule for all fresh poultry, the label is also required to carry a handling statement, “*Keep Refrigerated*” or “*Keep Frozen*,” as appropriate.

Under the rule, only accurate and documented labeling claims about irradiation are allowed. For example, the label could say “*Irradiated to Control Foodborne Bacteria*,” but not “*pathogen free*,” or “*extended shelf life*.”

Public Health Benefits

Poultry irradiation could play a significant role in preventing foodborne illness. Improper cooking and handling of contaminated poultry has been identified as a significant cause of illness; poultry irradiation has been shown to be a safe and effective treatment for reducing contamination on raw products.

How Poultry Irradiation Could Work

FSIS expects, for the near future, that most poultry irradiation will take place in federally inspected irradiation facilities that only perform that function, rather than in typical inspected poultry plants. Prepackaged poultry will be shipped under refrigeration to the plant, where pallets or containers of individually wrapped packages will be removed from the trucks and placed on a conveyor. The conveyor will pass into the irradiation “*chamber*,” where the poultry will be exposed for a pre-set time to absorb the correct dose of ionizing radiation.

The three types of irradiation FDA approved for poultry are gamma radiation, electron radiation and X-ray. Under FDA’s approval and USDA’s proposal, the radiation dose absorbed by the poultry and its packaging will be no less than 1.5 kiloGray (kGy) and no more than 3.0 kGy.

The rule requires that irradiation facilities meet safety standards and have quality controls to ensure proper handling and licensing of the radiation source and the safety of employees and the environment. Quality controls must be in place to ensure that poultry is processed correctly (including temperature and irradiation controls, packaging requirements, and steps to keep treated poultry separated from untreated poultry).



Foods That Can Be Irradiated In The United States

Dose Range	Purposes
Low-dose to 1 kiloGray (100 kilorads)	Control trichina parasite in fresh pork; Inhibit growth, maturation in fruits, vegetables, mushrooms, other fresh foods Control insects, mites, other arthropod pests in food
Medium-dose to 10 kiloGray (1,000 kilorads or 1 megarad)	Control microorganisms in dried enzymes Control bacteria in poultry that cause foodborne illness
High-dose above 10 kiloGray (above 1,000 kilorads or 1 megarad)	Control microorganisms in herbs, spices, teas and other dried vegetable substances

Dose: The international unit for quantifying the amount of radiation absorbed by a substance is the Gray (Gy). However, more people are more familiar with the older unit — kilorad (krad). A kilorad is 1,000 rads, and a Megarad is 1 million rads or 1,000 kilorads. The word “rad” stands for “radiation absorbed dose.” 100 rad = 1 Gy.

Packaging Requirements

Under the rule, only FDA-approved packaging materials--approved for use during irradiation--may be used. Fresh poultry must be packaged *before* it is irradiated, because even irradiated poultry could become contaminated if it is in the open, exposed to bacteria. FSIS inspectors must ensure that poultry plants have provided properly sealed packages to the irradiating facility.

To prevent cross-contamination from occurring, the packaging material must keep out liquids and microorganisms. However, the material must also allow air to enter the package, because airtight packaging may create an environment in which *Clostridium botulinum* bacterial spores that might be present could become active and produce the toxin that causes botulism.

Spoilage Bacteria

After irradiation at the approved dose, FDA determined enough spoilage-producing microbes would survive to provide warning signs of spoilage before any *C. botulinum* present could make the poultry toxic. FDA concluded, therefore, that “...irradiation of poultry at 3 kGy does not result in any additional health hazard from *C. botulinum*.”

The Rulemaking Process

Irradiation is a technical process. Nevertheless, sources of radiation are considered “*food additives*” under the Food, Drug, and Cosmetic Act. Thus, poultry irradiation had to be approved first by the FDA. Then, FSIS, under the meat and poultry inspection laws, undertook rulemaking.

The Rulemaking Process (continued)

FDA Review and Approval of the FSIS Petition. On October 24, 1986, FSIS petitioned FDA to permit irradiation of retail-packaged frozen or fresh, uncooked poultry and mechanically separated poultry product. FDA also received a petition from Radiation Technology, Inc.

In reviewing the merits of the petitions, FDA evaluated toxicity studies on irradiated chicken, reports on the efficacy of the process and on the microbiological safety of irradiated poultry, and studies of the nutritional adequacy of the irradiated product.

FDA Finds Poultry Irradiation Safe and Effective. On May 1, 1990, FDA published its approval of poultry irradiation, concluding that at the absorbed dose of 3 kGy, irradiation does not pose a safety hazard to consumers and is effective in reducing bacterial levels — particularly of such illness-causing bacteria as *Salmonella* and *Campylobacter*. Furthermore, FDA concluded consuming irradiated poultry would not have an adverse impact on the nutritional value of a consumer's diet.

FSIS Develops Proposal to Permit Poultry Irradiation. After FDA approved the process in 1990, FSIS began developing this proposed rule.

FSIS Proposes Irradiation of Poultry. On May 6, 1992, FSIS proposed a rule to permit irradiation of raw, packaged poultry to control foodborne pathogens such as *Salmonella*, *Campylobacter*, and *Listeria monocytogenes*.

FSIS Approves Irradiation of Poultry. On September 21, 1992, FSIS approved the poultry irradiation rule.

Public Comments

In its May 1992 proposal on poultry irradiation, FSIS invited public comment. The agency received 1,062 comments in the 60-day comment period. Approximately half the comments favored the proposal, and half did not.

Many of the commenters who favored the rule were physicians or other health professionals. They supported the safety and endorsed poultry irradiation as an effective way to reduce foodborne illness.

Those who objected to the rule expressed concerns about worker, environmental and consumer safety. In the final rule, FSIS reviewed these concerns and clarified issues about worker and environmental safety. As the purpose of FDA's review, which culminated in its 1990 rule, was to address the safety question, FSIS focused on how irradiation could be used effectively on fresh poultry.

Marketing Irradiated Poultry

Irradiation facilities must apply for FSIS approvals — including approval of the facility, quality controls, and irradiation label. Only after all those steps are followed may irradiated poultry be marketed. The market demand for the product will determine the extent to which the technology is used. The cost has been estimated at about 1.5¢ per pound.

Permitting irradiated poultry could increase the Nation's exports to countries interested in buying irradiated poultry from the United States.

Protecting FSIS Inspectors

Irradiation plants are responsible for proper controls to prevent FSIS employees from exposure to radiation. For instance, because people cannot be in the chamber with the radiation source, each radiation area would have to be "*conspicuously posted*" with appropriate signs and/or barriers. Under the rule, if a plant violates safe work practices, FSIS will withdraw its inspectors, a step that will immediately halt operations.

Protecting FSIS Inspectors (continued)

FSIS will provide specialized safety and radiological health training for its employees assigned to irradiation facilities. In addition to oversight by other Federal agencies, FSIS also will ensure safe and healthful working conditions for its employees through a variety of other controls — including monitoring and maintaining records of radiation exposure.

Application for Inspection

Under FSIS rules, poultry plants that slaughter, cut up and package poultry for interstate commerce must have a Grant of Inspection. If such plants wish to add irradiation capabilities, however, under the rule the new operations also must meet the new quality control (QC) guidelines.

Irradiation facilities whose only function is to irradiate pre-packed poultry must meet the necessary sanitation, facility, and operating requirements of existing regulations and must have an FSIS-approved QC system.

Under the rule, irradiation facilities also must verify to FSIS that they have met the requirements of all appropriate agencies. Several agencies are involved: the Nuclear Regulatory Commission (NRC), the Occupational Safety and Health Administration (OSHA), the National Institute of Standards and Technology (NIST) and the FDA. Also, NRC and OSHA can authorize State agencies to regulate radiation facilities, including compliance and safety inspections.

Quality Control System

Irradiation facilities must develop and follow a FSIS-approved QC system including:

Facility and Licensing Requirements: The plant must document its licensing by NRC, OSHA, or appropriate State authorities. Also, the facility must meet certain poultry inspection regulations. In addition, if the plant has no permanent refrigerated storage capacity, it must ensure adequate refrigeration during poultry irradiation.

Training: The plant must document that its personnel will operate under supervision of a trained person. Training must be sufficient and include: QC, food technology, irradiation process, and radiation health and safety.

Poultry Product and Packaging Material: The QC program must identify criteria to ensure the poultry receives an absorbed dose within the required range. The criteria relate to: the type of product (including its size, thickness, weight, and cut); the bulk density (the mass divided by its total volume); the proper packing configuration within the package; and the proper configuration of the entire packaged product (size, shape, number, and weight of the units on a pallet or container to be transported through the radiation chamber).

A guaranty or statement of assurance must accompany each shipment assuring the packaging material complies with the law and that the material is air-permeable, but excludes moisture and microorganisms from penetrating its barrier.

Dosimetry (Measuring Radiation): The QC system must include the American Society of Testing and Materials procedures and equipment used for measuring the dose of ionizing radiation absorbed by the product. To verify the correct dosage has been absorbed, measurements must be made on at least the first, middle, and last unit in each lot of poultry. The plant must demonstrate the accuracy of its dosimetry (measuring) system. Furthermore, the facility will be expected to show their system is calibrated every twelve months to NIST standards.





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Quality Control System (continued)

The QC system must have a means of ensuring that products do not receive more than the maximum allowed absorbed dose. Irradiation is permitted in more than one treatment as absorbed dose is cumulative, provided treatments are applied within the same day and if documentation is such that it assures the correctness of the total absorbed dose.

Labeling: The QC system must ensure proper labeling, as spelled out in the proposal.

Handling, Storage, and Transportation: The QC system must ensure that packages of poultry are intact; that the poultry is kept at appropriate temperatures throughout radiation processing and shipment; that procedures are spelled out for handling improperly irradiated or packaged poultry; that procedures are spelled out for preventing cross-contamination, re-irradiation, and mixing of irradiated and unirradiated products.

Corrective Action: The QC system must include procedures to correct failures and to prevent problems from reoccurring.

Recordkeeping

Under the proposal, irradiation plants must maintain for two years a written record of the QC system, their monitoring activity, and corrective actions taken.

Food Handling Education

Safe food handling would continue to be necessary for irradiated foods. USDA believes there is no such thing as too much food safety education. FSIS outreach includes information especially to benefit those most vulnerable to foodborne illness — the very young, the elderly, the immunocompromised, and for certain diseases pregnant women and their fetuses. FSIS also operates a nationwide toll-free Meat and Poultry Hotline (1-800-535-4555) that now reaches nearly 100,000 persons every year.

For more information about irradiation, contact:



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For more information about irradiation and safe food handling, contact:

USDA toll-free Meat and Poultry Hotline	1-800-535-4555
(in the Washington, D.C. area, call 202-720-3333)	